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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,382	02/19/2004	Hosheng Tu	GLAUKO.1C2C2	3584
20995 7590 02/23/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER WIEST, PHILIP R	
			ART UNIT	PAPER NUMBER
			3761	
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		02/23/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 02/23/2007.

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Office Action Summary	Application No. 10/782,382	Applicant(s) TU ET AL.	
	Examiner Phil Wiest	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/15/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Yu et al. (6,544,249). Yu et al. (hereafter Yu) discloses an apparatus that includes a microfistula tube (i.e. implant) having an outflow portion and an inflow portion in combination with an applicator configured to releasably hold at least a part of the implant (see figures 2-5). Preferably the microfistula tube can be placed along a passage from the anterior chamber to Schlemm's canal. See col. 2, lines 59-61 and col. 7, lines 35-55. With respect to the recitation of a "treatment kit" in the preamble, this does not impart any further structure in the claim to distinguish the structure to be a kit per se and therefore has been treated as a limitation of intended use. As such, it has not been given any patentable weight since it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (249) in view of Lynch et al. (6,827,700). Yu et al. (hereafter Yu) discloses the invention substantially as claimed, however, fails to disclose specifically that the implant is substantially L-shaped. Lynch et al. discloses a glaucoma shunt (i.e. implant) that may be substantially L-shaped (see figures 1-5). At the time of the invention, it would have been an obvious design choice to modify the shape of microfistula tube of Yu to be substantially L-shaped as taught by Lynch to provide greater patency of the implant when disposed in the body would be within the level of ordinary skill in the art.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

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by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1 and 2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, and 5 of copending Application No. 11/121584 (PGPubs 2005/0192527). Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a combination of an implant and an actuator for introducing the implant into the eye.

8. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claim 3 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 5 of copending Application No. 10/634,213 in view of Lynch et al. ('700).

10. Claim 5 of the patent discloses an instrument for delivering implants into the body, wherein the implants are held within the body of the instrument. While the application '213 claim 5 discloses the invention substantially as claimed, it fails to

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disclose specifically that the implant is substantially L-shaped. Lynch et al. discloses a glaucoma shunt (i.e. implant) that may be substantially L-shaped (see figures 1-5). At the time of the invention, it would have been an obvious design choice to modify the shape of the implant of the copending claim 5 to be substantially L-shaped as taught by Lynch to provide greater patency of the implant when disposed in the body would be within the level of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

11. Applicant's arguments filed 11/15/06 have been fully considered but they are not persuasive.

12. Applicant argues that Yu does not disclose each and every limitation recited in claim 1. Applicant argues that Yu does not disclose that the axes of the inflow and outflow portions are disposed at an angle to one another. However, Yu teaches that the microfistula implant is made of a gelatin material (Column 5, Lines 60-67), which has a degree of flexibility, inherently melts when heated, and become gel-like when exposed to water. Therefore, the implant is fully capable of being disposed in the anterior chamber of the eye at any angle depending on its rigidity and anatomical specificities of the eye.

13. Applicant further argues that the applicator disclosed by Yu is not configured to be used with an implant having an inflow portion wherein the axes of the inflow and outflow portions are disposed at an angle. Although the applicator is straight, the

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implant is capable of being housed within the applicator and still be disposed within the eye because of its flexible nature (as discussed above).

14. Regarding the 103(a) rejection of Claim 3, Applicant argues that there is no motivation to combine the implant of Yu with the L-shape of Lynch. Because Yu discloses that the implant is made of gelatin and is therefore flexible, it is capable of being disposed in the eye such that there is an angle between the inlet and outlet axes. A flexible implant that has a basic L-shape (such as that of Lynch) would be capable of being straightened and inserted into a straight applicator. Therefore, the applicator is fully capable of being used with an L-shaped microfistula implant that was made of gelatin. Doing this would combine the benefits of having an L-shaped implant with the ability to inject the implant with a tube-shaped injector.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235.

The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW
2/7/07

TATYANA ZALUKAEVA
SUPERVISORY EXAMINER



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